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Attachment B: Summary of Safety and Effectiveness Information

Synthes (USA)
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Synthes Sterile 4.5 mm Cannulated Screws are compared to Synthes 4.0 mm Cancellous Screws.

Synthes 4.5 mm Cannulated Screws are intended for fracture fixation of long bones and long bone fragments. Synthes 4.5 mm Cannulated Screws are available in various thread length configurations (partially or fully threaded). The 4.5 mm Cannulated Screw features self-drilling/self-tapping flutes and cancellous threads for use in cancellous bone. The screws are used in conjunction with a guide wire for precise placement in bone. Synthes 4.5 mm Cannulated Screws are manufactured from stainless steel or Ti Alloy.

Synthes 4.5 mm Cannulated Screws will be provided sterile, gamma radiation will be used to sterilize the device.

Based on mechanical testing, Synthes 4.5 mm Cannulated Screws are at least equivalent to Synthes 4.0 mm Cancellous Screws.